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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 8
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Application Number: 08/833096
Filing Date: April 4, 1997
Appellant(s): Ralph A. Nelson et al.

Jack E. Dominik
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed January 4, 1999.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The issue with regard to the enablement for a composition having a molecular weight of 100 or less is still before the Examiner, as that claim has not been canceled.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-21, 24-33, 44-45, 49-51, and 63-66 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is substantially correct. Claim 64 should be included and reads:

64. A pharmacological composition of matter comprising the blood or urine of fasting bears, which bear had been fasted for two weeks or more, said composition having a molecular weight of 100 or less, which composition when injected into a mammal other than a bear, which mammal has been ovariectomized, produces by comparison to an ovariectomized mammal not treated with said composition of matter, enhanced bone growth.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 63-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising deproteinated fasting bear serum or urine and the fractions disclosed in the specification, does not reasonably provide enablement for a pharmacological composition comprising 24,25-dihydroxyvitamin D3 or a composition having a molecular weight of 100 or less. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While applicants show the effects of the deproteinated fasting bear serum or urine, it is unclear and not predictable that 24,25-dihydroxyvitamin D3 or a composition having a molecular weight of 100 or less are the active ingredients responsible for the bone formation, especially in view of the wide and varied quantity and quality of the components of the individual fractions of the deproteinated serum or urine. One skilled in the art would be unable to predict that isolation of merely the above referenced components would result in a composition having the desired stimulation of bone formation.

2. Claims 1-21, 24-30, 44-45 and 63-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the claims, the phrase "having the characteristics"" fails to distinctly describe the composition, as it is unclear to what characteristics the phrase such that the metes and bounds of the claims are not clear. In the claims, it is unclear what is meant by the term "ursus-like". Further, the phrase "resembling the characteristics of a bear derived isolate" fails to distinctly describe the composition, as it is unclear what constitute "resembling" and a "bear derived isolate". In claim 4, it is unclear what is meant by the phrase "at least one vital sign of behavioral modification substance"; further, it is not clear what is meant by the term "metabolites". In claim 8, it is not clear what is meant by the phrase "having the characteristics of an isolate of whole blood or whole urine sample". In claims 10 and 11, the phrase "having the characteristics of the deproteinated urine or blood serum isolate of fasting bear" is unclear. In claims 12-15, the

term "substance" is unclear; use of statutory language "composition" or "compound" is suggested. In claim 12, the phrase "having the characteristics of a sample of whole blood or whole urine taken from a fasting black bear" is also unclear. In claim 13, it is unclear what is meant by the term "signature exhibited in the deproteinated isolate of urine or blood". Claims 1-15 and 18 are deemed vague and indefinite as the claims are defined by functional language; the claims are defined by what the composition does and not by what it is. Further, comparisons by use of the phrase "having the characteristics" are vague as there is no way to determine the required characteristics of the compared "isolate". Also, there is no preamble language and no transitional phrasing. It is unclear as to exactly what Applicants consider their invention. In claim 17, the term "derived" is unclear; use of the term "obtained" is suggested. Further, there is no transitional phrasing so that the metes and bounds of the claims are unclear; this is true also for claims 18 and 19. In claims 44 and 45, it is unclear what is comprised by the term "active substance".

3. Claims 32-33, 49 and 51 are rejected under 35 U.S.C. 101 as being a substantial duplicate of claims 31, 48 and 50, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

(11) Response to Argument

Claim Rejections - 35 USC § 112

Applicants argue that because DBI is shown to contain D3, therefore D3 is responsible for the effect of DBI. However, such has not been shown. DBI contains other components which have not been identified and it is reasonable, since DBI is obtained from urine or serum, that it contains other components of molecular weight of 100 or less. There is no disclosure regarding these components and one of skill in the art would need to engage in undue experimentation to identify and assay each component to determine their activity. Further, at page 28, the specification states "Considered by most a metabolite of Vitamin D that has no metabolic action and normally excreted from the body, the 24,25 form actually stimulates bone deposition." Therefore, absent a showing to the contrary, one of skill in the art would not be motivated to produce a pharmacologic composition comprising the 24,25 form of Vitamin D3. As this discovery appears to be part of Applicants' invention and as Applicants describe the activity of the 24,25 form as surprising and unexpected, absent a showing, this area of the prior art is considered unpredictable requiring a further showing.

4. Claims 1-21, 24-30, 44-45 and 63-66 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants argue that the term "chemistry similar to" "are ubiquitous terms in patent

claims" and argues that the term is enabled. However, there is nothing in the specification which defines the compared composition, i.e. a bear derived isolate. Applicants merely describe the composition as a product by process so therefore, per the disclosure, they do not really know what is present in the composition. How, therefore, can one skilled in the compare its chemistry if its chemistry is unknown? In the claims, the phrase "chemistry similar to" also fails to distinctly describe the composition, as it is unclear to what similarities or what chemistry the phrase such that the metes and bounds of the claims are not clear. With regard to the term "ursus-like", the term "ursus" is a bear, how can a chemical be "bear-like"? Applicants may be their own lexicographer; however, Office personnel must rely on the applicant's disclosure to properly determine the meaning of terms used in the claims. Markman v. Westview Instruments , 52 F.3d 967, 980, 34 USPQ2d 1321, 1330 (Fed. Cir.) (in banc), aff'd, ** U.S. **, 116 S. Ct. 1384 (1996). See, e.g., In re Paulsen , 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (inventor may define specific terms used to describe invention, but must do so "with reasonable clarity, deliberateness, and precision" and, if done, must "'set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change" in meaning) (quoting Intellicall, Inc. v. Phonometrics, Inc. , 952 F.2d 1384, 1387 - 88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992)). If an applicant does not define a term in the specification, that term will be given its "common meaning." Paulsen at 1480, 31 USPQ2d at 1674. It is simply not clear with regard to an undefined extract of bear blood or urine how one skilled in the art would be able to compare another composition and find it "ursus-like".

The arguments with regard to "having a chemistry similar to" and "ursus-like" are equally applicable to the phrase "resembling the characteristics of a bear derived isolate" the phrase "at least one vital sign of behavioral modification substance"; further, it is not clear what is meant by the term "other substances". As stated previously, if the composition is not characterized in a chemical manner, how can one skilled in the art compare it chemically to any other composition. In claim 13, it is unclear what is meant by the term "signature marker exhibited in the deproteinated isolate of urine or blood". To what marker does the claim refer? Claims 4-8 are deemed vague and indefinite as the claims are defined by functional language; the claims are defined by what the composition does and not by what it is. Just as claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function, (In re Danley, 120 USPQ 528, 531 (CCPA 1959). "Apparatus claims cover what a device is, not what a device does ."(emphasis in original) Hewlett - Packard Co . v. Bausch & Lomb Inc ., 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)), so too a claim to a composition should in the least recite some aspect of what the composition is rather totally by what it does. As such, a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. Whether or not the functional limitation complies with 35 U.S.C. 112, second paragraph is a different issue from whether the limitation is properly supported under 35 U.S.C. 112, first paragraph or is

distinguished over the prior art. In this case, claim 4-8 merely claim "evidence" of a substance present in the blood or urine of a fasting bear; what is comprised by this "evidence" is totally unknown.

Double Patenting

5. Claims 32-33, 49 and 51 remain rejected under 35 U.S.C. 101 as being a substantial duplicate of claims 31, 48 and 50, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicants argue that the claims are not the same because they are directed to different effects upon administration; however, as far as can be determined from the specification and the claim language, the compositions are the same. They are merely describing inherent effects.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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